

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

EXELA PHARMA SCIENCES, LLC, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	
)	Civil Action No. 1:12-cv-00469
DAVID J. KAPPOS, Under Secretary of)	(LO/JFA)
Commerce for Intellectual Property and)	
Director of the United States Patent and)	
Trademark Office,)	
)	
UNITED STATES PATENT AND)	
TRADEMARK OFFICE,)	
)	
Defendants.)	
_____)	

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' AND INTERVENORS'
MOTION FOR RECONSIDERATION

Pursuant to Local Rule 7(F)(1), Defendants and Intervenors, through the undersigned counsel, respectfully submit this reply memorandum in support of their Motion for Reconsideration.

INTRODUCTION

In their Opposition, Plaintiffs Exela Pharma Sciences, LLC, Exela PharmaSci, Inc., and Exela Holdings, Inc. ("Plaintiffs") do not dispute that the Fourth Circuit's decision in *Hire Order Ltd. v. Marianos*, -- F.3d --, 2012 WL 4950863 (4th Cir. Oct. 18, 2012),¹ constitutes controlling authority on the issue of timeliness or that this Court may reconsider its interlocutory order denying Defendants' Motion to Dismiss pursuant to Federal Rule of Civil Procedure 54(b).

¹On the date this brief was filed, the appellants in *Hire Order* filed a petition for rehearing and rehearing *en banc*.

Instead, Plaintiffs argue that interpreting *Hire Order* to render Plaintiffs' suit untimely is contrary to well-settled Supreme Court precedent and would lead to absurd results. Moreover, Plaintiffs contend that *Hire Order* is distinguishable because, unlike here, the appellants in *Hire Order* raised a purely facial challenge.

Plaintiffs' arguments, however, simply ignore the only relevant issue in this case—*i.e.*, under *Hire Order*, the statute of limitations in an Administrative Procedure Act ("APA") suit commences on the date of "final agency action" regardless of the date of injury. Plaintiffs point to no "final agency action" within the last six years that would make this lawsuit timely, and they do not even address the fact that the Fourth Circuit in *Hire Order* rejected the exact arguments raised by Plaintiffs here. Nor do Plaintiffs demonstrate that the holding of *Hire Order* is limited to purely facial challenges. Indeed, Plaintiffs offer no meaningful distinction between the facial challenge raised in *Hire Order* and the claims they raise here. Accordingly, their challenges to the United States Patent and Trademark Office's ("USPTO") decision reviving SCR Pharmatop's PCT/FR01/01749 application ("2003 Revival Decision") and 37 C.F.R. § 1.137(b) are untimely.

Plaintiffs also have cited no authority under which USPTO's 2012 Letter response to their self-styled petition for reconsideration of the 2003 Revival Decision restarted the statute of limitations and rendered timely their underlying challenges to the 2003 Revival Decision and § 1.137(b). Moreover, Plaintiffs' belated effort to recast their Complaint as a challenge to the 2012 Letter response fails at the threshold because they cannot demonstrate that it was properly pled, and as clearly stated in the authority cited by Plaintiffs themselves, that decision is unreviewable because it raises a purely legal challenge that is not based on new evidence or

changed circumstances. *See I.C.C. v. Brotherhood of Locomotive Eng'rs*, 482 U.S. 270, 278-79 (1987). Accordingly, all of Plaintiffs' claims should be dismissed.

ARGUMENT

I. PLAINTIFFS FAIL TO DEMONSTRATE THAT THEIR CASE IS TIMELY UNDER *HIRE ORDER*.

1. As explained in Defendants' and Intervenor's opening brief, the Fourth Circuit for the first time held in *Hire Order* that for purposes of APA actions, the six-year statute of limitations in § 2401(a) begins to run on the date of final agency action even if, like here, the plaintiff is injured by that action at a later date. Because Plaintiffs can point to no final agency action in the last six years that would render their action timely under *Hire Order*, they ignore the plain import of that case and argue that the statute of limitations must commence on the date of injury under "controlling precedent" to avoid absurd results. Plaintiffs' arguments, however, were already expressly rejected by the *Hire Order* court.²

As explained in Defendants' and Intervenor's opening brief, Dkt. No. 49 at 8-10, appellants in that case—firearms distributors who became federal firearms licensees in 2008—raised an APA challenge to a 1969 revenue ruling. *Hire Order*, 2012 WL 4950863, at *1. Like Plaintiffs here, they argued that under controlling Supreme Court precedent—including *Bay Area Laundry & Dry Cleaning Pension Trust Fund v. Ferbar Corp.*, 522 U.S. 192 (1997) and *Crown Coat Front Co. v. United States*, 386 U.S. 503, 511 (1967)—their action was timely

²To the extent Plaintiffs argue that *Hire Order* was wrongly decided or is inconsistent with controlling authority, that is not for this Court to determine. "It is well established that a federal district court must generally apply an interpretation of law articulated by its circuit court of appeals." *See Gacy v. Welborn*, 994 F.2d 305, 309 (7th Cir.1993) (noting that "[o]urs is a hierarchical judiciary," and that lower court judges are bound to apply the existing law as interpreted by the higher courts).

under § 2401(a) because a cause of action first “accrues” when the plaintiff is injured. *Hire Order Ltd. v. Marianos*, Appellant’s Br., 2011 WL 5040509, at *3-*4 (“Afton’s and Privott’s right of action first accrued in 2008 when they obtained their federal firearms licenses because the ‘right of action of which § 2401(a) speaks’ is ‘the right to file a civil action in the courts against the United States.’” (quoting *Crown Coat*, 386 U.S. at 511) (citing *Bay Area Laundry*, 522 U.S. at 201)). They further argued, like Plaintiffs here, that to hold otherwise would lead to absurd results—*i.e.*, that the appellants would be prevented from challenging the revenue ruling even though they were not in existence within six years of the ruling’s promulgation. *Id.* at *10 (“To deny Afton and Privott the opportunity to challenge Revenue Ruling 69-59 is [sic] approve the absurd result that only a person who was licensed within six years after Revenue Ruling 69-59 was issued could challenge it.”). And the Fourth Circuit expressly rejected those arguments, holding that “[t]he contention of *Hire Order* and *Privott* that their cause of action did not accrue until they became federally licensed firearms dealers in 2008 utterly fails.” *Hire Order*, 2012 WL 4950863, at *2 (emphasis added).

Plaintiffs’ challenge is indistinguishable in all material respects from the challenge raised by the appellants and deemed untimely in *Hire Order*. That is, their claim that they were first injured by the 2003 Revival Decision when Intervenors sued for patent infringement in 2011 is directly analogous to the dealers’ claim in *Hire Order* that they were not injured by the 1969 revenue ruling until they received their federal firearms licenses in 2008. In neither case did the challenged agency action occur within six years of the complaint, and in neither case was that action applied against the plaintiff. As a result, the *Hire Order* court found the action untimely, and for the same reasons, Plaintiffs’ action here is untimely.

In effect, Plaintiffs act as if *Hire Order* never happened, citing the same case law and making the same arguments as they did in their opposition to Defendants' motion to dismiss. *Compare* Dkt. No. 51 at 4-7 *with* Dkt. No. 11 at 14-17. That is, in arguing that controlling precedent supports their argument that the statute of limitations commenced on the date of their injury, Plaintiffs simply ignore the fact that the appellants in *Hire Order* *also claimed they were injured within six years of their lawsuit* and that the Fourth Circuit still found their action untimely. And the *Hire Order* court found nothing "absurd" or "odd," *see* Dkt. No. 51 at 8-9, about the fact that the appellants' challenge was time-barred even though, as the appellants had argued, they did not exist during the long-ago period when a challenge to the 1969 revenue ruling would have been timely.

Indeed, Plaintiffs find themselves in their current position not because well-settled APA timeliness principles based on "final agency action" have led to an untenable result, but because their alleged injury is divorced from the "final agency action" they challenge. Put differently, timeliness and standing are distinct concepts, and when a plaintiff's injury is decoupled from a challenged agency action—as is the case here, where Plaintiffs bring a collateral attack to an agency decision regarding Intervenorors—that injury must have occurred before the time to challenge the agency action has expired in order to bring suit. *See also Shiny Rock Min. Corp. v. United States*, 906 F.2d 1362, 1365 (9th Cir. 1990) ("[T]o accept the suggestion that standing to sue is a prerequisite to the running of the limitations period" in an APA action "would render the limitation on challenges to agency orders . . . meaningless."). This is precisely what the reasoning of *Hire Order* dictates.

Plaintiffs also ignore the fact that in reaching its conclusion that the appellants' action

was untimely, the Fourth Circuit in *Hire Order* distinguished *Bay Area Laundry and Crown Coat*. See *Hire Order*, 2012 WL 4950863, at *2. According to Plaintiffs, those cases mandate that the statute of limitations cannot commence until the date of injury. See Dkt. No. 51 at 4-5. The *Hire Order* court, however, denied that very argument in finding that timeliness is calculated from the date of final agency action in APA cases. *Hire Order*, 2012 WL 4950863, at *2. Indeed, other than *Jersey Heights Neighborhood Association v. Glendening*, 174 F.3d 180 (4th Cir. 1999), none of the cases Plaintiffs rely upon to support their timeliness theory involve the timeliness of APA actions and are therefore inapplicable to this case. See Dkt. No. 51 at 4-9.³

Moreover *Hire Order* is plainly not inconsistent with *Jersey Heights*. In *Jersey Heights*, the appellants were injured at the time final agency action occurred:

Whether the residents characterize their injury as the discrimination alone or as the resulting siting decision, that injury had been sustained by the time the ROD [Record of Decision] issued in 1989. Consequently, we agree with the district court that the August 17, 1989 ROD was the final agency action for the Bypass siting decision. . . . The Neighborhood Association's APA claims therefore accrued on that date and lapsed six years later, in 1995.

³See *Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 545 U.S. 409, 418-19 (2005) (analyzing the False Claims Act's statute of limitations); *Reiter v. Cooper*, 507 U.S. 258, 267 (1993) (analyzing the statute of limitations set forth in 49 U.S.C. § 11706); *TRW Inc. v. Andrews*, 534 U.S. 19, 34 (2001) (analyzing the statute of limitations set forth in the Fair Credit Reporting Act); *Clark v. Iowa*, 87 U.S. 583, 589 (1875) (analyzing an Iowa statute of limitations relating to contract actions); *Ladd v. United States*, 630 F.3d 1015 (Fed. Cir. 2010) (analyzing the statute of limitations set forth in 28 U.S.C. § 2501); *United States v. Minor*, 228 F.3d 352, 353 (4th Cir. 2000) (deciding under the Fifth Amendment "whether the United States provided adequate notice to a prisoner in government custody before it declared property owned by that prisoner administratively forfeited"); *Franks v. Ross*, 313 F.3d 184 (4th Cir. 2002) (involving state, federal civil rights, and federal constitutional claims); *White v. Sun Life Assurance Co. of Canada*, 488 F.3d 240, 245 (4th Cir. 2007) (involving an ERISA claim); *In re Carrington Garden Assocs.*, 258 B.R. 622 (E.D. Va. 2001) (involving a Chapter 11 debtor's adversarial proceeding against the United States).

174 F.3d at 187. In *Hire Order*, on the other hand, the final agency action—the promulgation of the 1969 revenue ruling—did not injure the appellants until much later. *Hire Order*, 2012 WL 4950863, at *2 (explaining that the appellants did not become federal firearms licensees subject to the 1969 revenue ruling until 2008). But in both cases, the Fourth Circuit found that the statute of limitations begins to run on the date of final agency action.

In arguing that *Hire Order* conflicts with *Jersey Heights*, Plaintiffs appear to conflate the concepts of timeliness and finality. In *Jersey Heights*, the Fourth Circuit first determined that § 2401(a)’s statute of limitations begins to run at the time of final agency action, and *then*, citing *Franklin v. Massachusetts*, 505 U.S. 788 (1992), analyzed whether the ROD was “final” based on whether “the agency ha[d] completed its decisionmaking process, and [whether] the result of that process [was] one that [would] directly affect the parties.” *Jersey Heights*, 174 F.3d at 186.⁴ Here, on the other hand, there can be no dispute that the 2003 Revival Decision constitutes final agency action. That is, the 2003 Revival Decision was final when rendered, not when Intervenor sued Plaintiffs eight years later. Thus, the finality analysis in *Jersey Heights* has no bearing on this case, and under both *Jersey Heights* and *Hire Order*, the statute of limitations commenced when the 2003 Revival Decision was issued.

2. Plaintiffs also contend that *Hire Order* does not apply here—and is not inconsistent with the “controlling precedent” it cites—because it applies only to purely facial challenges. *See* Dkt. No. 51 at 10-14. But Plaintiffs fail to demonstrate why *Hire Order*—which rejected the

⁴As explained in Defendant’s opening brief, both *Franklin* and *Golden & Zimmerman, L.L.C. v. Domenech*, 599 F. Supp. 2d 702 (E.D. Va. 2009)—which Plaintiffs also cite—analyze finality without addressing what event triggers the six-year statute of limitations in § 2401(a).

argument that the statute of limitations in an APA action commences on the date of injury—is so limited. In other words, Plaintiffs offer no meaningful distinction between *Hire Order* and this case.

Foremost, to the extent Plaintiffs argue that the six-year statute of limitations does not apply to as-applied challenges, the argument borders on the frivolous. *See* Dkt. No. 51 at 4 (arguing that it is “well-settled law” that “[w]hen there is no facial challenge, the statute of limitations does not bar judicial review of any agency action applying a rule beyond the initial six-year period for bringing a facial challenge” (emphasis in original)). Plaintiffs cite no case law to support this conclusion, and the Fourth Circuit held in *Jersey Heights* that § 2401(a) applies to any APA challenge to a “final agency action.” *See Jersey Heights*, 174 F.3d at 187 (“[W]e agree with the district court that the August 17, 1989 ROD was the final agency action for the Bypass siting decision. . . . The Neighborhood Association’s APA claims therefore accrued on that date and lapsed six years later, in 1995.”). Put differently, § 2401(a) sets the same six-year deadline for both facial and as-applied APA challenges, and the only challenge by Plaintiffs here is to final agency action that occurred well over six years before the Complaint was filed.

Moreover, Plaintiffs contend that a purely facial challenge must be brought within six years of a regulation’s promulgation because “an interested complainant has a legally cognizable injury the moment the agency issues the rule.” Dkt. No. 51 at 12-13. However, neither *Hire Order* nor any other case of which undersigned counsel is aware has reached that conclusion. To the contrary, the Fourth Circuit in *Hire Order* held that “[a] cause of action governed by § 2401(a) accrues or begins to run at the time of ‘final agency action,’” *Hire Order*, 2012 WL

4950863, at *2, and that for purposes of a challenge to an agency regulation, “the limitations period begins to run when the agency publishes the regulation,” *id.* (quoting *Dunn-McCampell Royalty Interest, Inc. v. Nat’l Park Serv.*, 112 F.3d 1283, 1287 (5th Cir. 1997)). In other words, the *Hire Order* court held that the statute of limitations commences in a facial challenge to a regulation on the date of promulgation because that constitutes the date of “final agency action,” not because injury occurs on that date.

Indeed, Plaintiffs’ argument conflicts with its own position that a statute of limitations cannot start running until a plaintiff is injured. That is, in *Hire Order*, the challenged revenue ruling was issued in 1969, and the appellants did not become federal firearms licensees until 2008. Thus, under Plaintiffs’ argument, either *Hire Order* was wrongly decided because the appellants could not have had a “legally cognizable injury the moment the agency issue[d] the rule,” Dkt. No. 51 at 12, or the date of injury is irrelevant with respect to facial challenges. Given that Plaintiffs do not appear to be arguing the former, the inherent contradiction in Plaintiffs’ argument demonstrates the weakness of their position. At bottom, the holding and reasoning of *Hire Order* are not limited to the specific type of challenge presented there—in *Hire Order*, the final agency action challenged was the promulgation of the 1969 revenue ruling, and here it is the 2003 Revival Decision, and in both cases, the plaintiffs’ claims were untimely even though the plaintiffs alleged they were injured by those final agency actions within six years of the suit.

3. Finally, even under Plaintiffs’ narrow reading of *Hire Order*, their lawsuit is untimely. As explained in Defendants’ and Intervenor’s opening brief, Dkt. No. 49 at 15, the regulation and statute at issue here were never applied *against Plaintiffs*. Rather, Plaintiffs raise a collateral

attack on an agency decision applying the regulation and statute to SCR Pharmatop. Thus, as explained *supra*, Plaintiffs’ alleged injury—the patent infringement suit in Delaware—is divorced from the “final agency action” being challenged here. And as a result, Plaintiffs’ raise a purely legal challenge that is directly analogous to the purely facial challenge in *Hire Order*.

That is, while Plaintiffs now attempt to avoid *Hire Order* by contending that they never intended to bring a facial challenge and that they plainly raise only an as-applied challenge, *see* Dkt. No. 51 at 18, Plaintiffs’ argument, boiled down to its essence, is that *the rule* applied in the 2003 Revival Decision—*i.e.*, that § 1.137(b) applies to all PCT applications abandoned under 35 U.S.C. § 371(d)—is unlawful, and that they were subsequently injured by that rule *even though the rule was never applied against them*. Indeed, Plaintiffs’ Complaint is entitled “Complaint for Declaratory and Injunctive Relief and *Petition for Review of Rulemaking*,” and Count IV is entitled “Unlawful Rules and Regulations.”⁵ The Complaint also asks, in the Request for Relief, that this Court “[i]ssue a declaratory judgment or other order holding that the USPTO *rules and regulations* allowing for the revival of an international patent application under the ‘unintentional’ standard are unlawful.” Moreover, Plaintiffs’ reliance in their Opposition on the vacated district court opinion in *Aristocrat Technologies Australia Pty. Ltd. v. International Game Technology*, 491 F. Supp. 2d 916 (N.C. Cal. 2007), *vacated on other grounds*, 543 F.3d 657 (Fed. Cir. 2008), demonstrates that their challenge to the 2003 Revival Decision is purely legal.⁶

⁵Plaintiffs’ Complaint did not identify the precise “Rules and Regulations” that they were challenging.

⁶Similarly, the arguments raised by Plaintiffs in their Motion for Summary Judgment are inconsistent with their position here that they bring only an as-applied challenge. That is,

Therefore, even if it is true, as Plaintiffs contend, that they do not argue that “37 C.F.R. § 1.137(b) is unlawful in every conceivable application,” Dkt. No. 51 at 11, their challenge to the 2003 Revival Decision is fundamentally no different from the purely facial challenge raised in *Hire Order*. See *Env’tl Protection Info. Ctr. v. Pac. Lumber Co.*, 266 F. Supp. 2d 1101 (N.D. Cal. 2003) (holding that the plaintiff’s action is untimely where it was not the subject of an enforcement action and “[d]espite [the plaintiff]’s attempt to cast this action as a substantive challenge to application of [a regulation], the plaintiff is directly challenging the legal validity of the regulation”). Accordingly, Plaintiffs’ suit is untimely.

II. USPTO’S 2012 LETTER DECISION DID NOT RESTART THE STATUTE OF LIMITATIONS CLOCK ON PLAINTIFFS’ CHALLENGE TO THE 2003 REVIVAL DECISION.

This Court, in denying Defendants’ motion to dismiss, left open the question of how USPTO’s 2012 Letter response to Defendants’ petition for reconsideration affected the timeliness of Plaintiffs’ challenge to the 2003 Revival Decision. See *Exela Pharma Scis., LLC v. Kappos*, No. 1:12-cv-469, 2012 WL 3638552, at *1 n.1 (E.D. Va. Aug. 22, 2012). That Letter response, rather than addressing the merits of the 2003 Revival Decision as Defendants had requested in their petition, stated that under USPTO rules and regulations, as well as the Patent Act and controlling case law, Defendants’ third-party petition was improper and would be stricken from the record. See A.R. at A1. As a result, as Defendants and Intervenor explained in their opening brief, Dkt. No. 49 at 16-20, that Letter response cannot restart the limitations

Plaintiffs challenge the application of § 1.137(b) to *all revivals* under § 371(d), not just the revival of SCR Pharmatop’s PCT application. See, e.g., Dkt. No. 41-1 at 8 (“35 USC § 371(d) is clear and unambiguous in requiring unavoidable delay for reviving international applications”). Put differently, Plaintiffs never argue that the 2003 Revival Decision was improper *with respect to Intervenor specifically*. Thus, Plaintiffs do not raise an as-applied challenge.

clock, and Plaintiffs' complaint fails to state a claim that USPTO's refusal to reconsider the merits of the 2003 Revival Decision was arbitrary and capricious.

As an initial matter, Plaintiffs' Opposition does nothing to refute Defendants' argument that they have failed to state claim regarding the propriety of USPTO's refusal to reconsider the 2003 Revival Decision. That is, Plaintiffs' Opposition merely confirms that their detailed, 16-page complaint contains a total of three references to such a claim, and nowhere does the Complaint even suggest how the agency acted arbitrarily and capriciously in refusing to reconsider Plaintiffs' third party petition challenging USPTO's revival decision. Put simply, Plaintiffs' have pled this case as a challenge to the merits of the 2003 Revival Decision, and not as a challenge to USPTO's refusal to reconsider that decision. And as even *I.C.C. v. Brotherhood of Locomotive Engineers*, 482 U.S. 270 (1987)—which Plaintiffs erroneously cite in support of their Opposition, *see infra*—confirms, those challenges are distinct. *Id.* at 278. (“When the Commission reopens a proceeding for any reason and, after reconsideration, issues a new and final order setting forth the rights and obligations of the parties, that order . . . is reviewable on its merits. Where, however, the Commission *refuses* to reopen a proceeding, what is reviewable is merely the lawfulness of the refusal.” (emphasis in original) (internal citation omitted)). Accordingly, Plaintiffs' conclusory allegations that the 2012 Letter response is arbitrary and capricious fail to state a claim, and thus this case should be dismissed in its entirety. *See Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009) (“[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to . . . [t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements.”).

Plaintiffs also entirely fail to demonstrate that the 2012 Letter response renders their

challenge to the 2003 Revival Decision timely such that this Court should address the merits of that nine-year-old decision. Indeed, other than one conclusory statement, *see* Dkt. No. 51 at 15, Plaintiffs do not even appear to argue this point.

As Defendants and Intervenors explained in their opening brief, Dkt. No. 49 at 19-20, the USPTO Letter response does not fall within any timeliness exceptions because it does not address the merits of the 2003 Revival Decision. *See, e.g., Wind River Mining Corp. v. United States*, 946 F.2d 710, 716 (9th Cir. 1991) (holding that a challenge to a recent agency decision upholding a longstanding prior agency decision was timely where the agency reconsidered the merits of that prior decision as applied to the plaintiffs within six years of the complaint). If a plaintiff could get judicial review of a long-settled agency decision simply by filing a perfunctory request for reconsideration with the agency regardless of whether the agency's statutes, regulations, and rules permitted such a request, timeliness principles—which ensure finality of agency decisions—would be meaningless. Indeed, the Fourth Circuit in *Hire Order* questioned the ability of parties to restart the limitations clock in this manner. *See* 2012 WL 4950863, at *3 n.2 (“We note that the case on which Hire Order and Privott heavily rely in making their alternative argument [that they can restart the limitations clock by filing a petition to reconsider the revenue ruling], may not provide as fulsome authority for their position as they suggest.” (citing *NLRB Union v. FLRA*, 834 F.2d 191, 196 (D.C. Cir. 1987); *Cronin v. FAA*, 73 F.3d 1126, 1131 n.3 (D.C. Cir. 1996))).

Instead, Plaintiffs argue on the merits that USPTO erred in refusing to reconsider the 2012 Letter response. *See* Dkt. No. 51 at 14-18. To the extent, however, that Plaintiffs' have stated a claim on this issue, the Court should not address the merits of whether the agency acted

properly in refusing to reconsider the 2003 Letter Decision in this briefing on Defendants’ Motion for Reconsideration. That is, should this Court determine that this case can proceed on the reconsideration issue—*i.e.*, the only timely issue mentioned in Plaintiffs’ Complaint—the Court should order the parties to agree to a merits briefing schedule limited to the propriety of the 2012 Letter response.⁷

But regardless, the cases cited by Plaintiffs in arguing that USPTO improperly refused to reconsider the 2003 Revival Decision—*i.e.*, *Locomotive Engineers* and its progeny—in fact support USPTO’s decision. As explained *supra*, the Supreme Court in *Locomotive Engineers* found that where an agency “refuses to reopen a proceeding”—as in this case—“what is reviewable is merely the lawfulness of the refusal.” 482 U.S. at 278 (emphasis in original). That is, “[a]bsent some provision of law requiring a reopening . . . the basis for challenge must be that the refusal to reopen was ‘arbitrary, capricious, [or] an abuse of discretion,’” *id.* (quoting 5 U.S.C. § 706(2)(A)), and “overturning the refusal to reopen requires a showing of the clearest abuse of discretion,” *id.* (internal quotation omitted). As a result, the Court found that refusals to reopen or reconsider are only reviewable if the petitions allege “new evidence” or “changed circumstances.” *Id.* That is, the petitions must allege “*facts* which through no fault of [the petitioner’s], the original proceeding did not contain.” *Id.* at 279 (emphasis added). “By contrast, where no new data but only ‘material error’ has been put forward as the basis for

⁷Even if this Court were to hold on the merits that USPTO’s refusal to reconsider the 2003 Revival Decision was arbitrary and capricious, the only appropriate relief would be a remand to the agency for a reconsideration of the merits of that decision. *See Locomotive Engineers*, 482 U.S. at 278 (“When the Commission reopens a proceeding for any reason and, *after reconsideration*, issues a new and final order setting forth the rights and obligations of the parties, that order . . . is reviewable on its merits.” (emphasis added)).

reopening, an appeal places before the courts precisely the same substance that could have been brought there by appeal from the original order.” *Id.* Accordingly, the Court held that “where a party petitions an agency for reconsideration on the ground of ‘material error,’ *i.e.*, on the same record that was before the agency when it rendered its original decision, an order which merely denies rehearing of the prior order is not itself reviewable.” *Id.* at 280 (internal quotation, citation, and alteration omitted).

Under *Locomotive Engineers*, USPTO’s 2012 Letter response is not reviewable. Plaintiffs’ petition merely alleged “material error” in the 2003 Revival Decision—*i.e.*, that USPTO incorrectly interpreted § 371(d) when it applied § 1.137(b) to revive SCR Pharmatop’s PCT application—such that it sought reconsideration “on the same record that was before the agency when it rendered its original decision.” *See* 482 U.S. at 279. And contrary to Plaintiffs’ arguments, they have failed to allege “*facts*” that were not before the agency at the time of the 2003 Revival Decision or any other “changed circumstances” such that USPTO is required to reconsider the merits of that decision. Indeed, Plaintiffs contend simply that reconsideration is required because they were not in existence at the time of the 2003 Revival Decision to raise a collateral attack, and the Northern District of California’s vacated, non-binding decision in *Aristocrat Technologies Australia Pty. Ltd. v. International Game Technology*, 491 F. Supp. 2d 916 (N.C. Cal. 2007), opined that the rule applied in the 2003 Revival Decision was improper. However, that Plaintiffs were unavailable to challenge the 2003 Revival Decision has nothing to do with the underlying substance of that decision because Plaintiffs can point to no new “facts” that would have changed the revival decision, and the Northern District of California’s vacated opinion has no binding effect and raised no new information regarding the propriety of that

decision. Accordingly, the cases cited by Plaintiffs in support of their contention that they fall within the exception to *Locomotive Engineers* are inapposite, and any challenge to the 2012 Letter response should be dismissed. *Cf. Jost v. Surface Trans. Bd.*, 194 F.3d 79, 85 (D.C. Cir. 1999) (applying the *Locomotive Engineers* exception because the petition was “based on inaccurate, incomplete and misleading information provided [to the agency]”); *Fritsch v. I.C.C.*, 59 F.3d 248, 251 (D.C. Cir. 1995) (applying the *Locomotive Engineers* exception because the petition “presented . . . new material accompanying the motion to reopen” and was “based on non-pretextual grounds of new matter or changed circumstances, and not merely on material error in the original agency decision”).

CONCLUSION

For these reasons, the Court should grant Defendants’ and Intervenor’s motion for reconsideration and dismiss this action with prejudice.

Respectfully submitted,

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DATED: November 27, 2012

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 27, 2012, I will file the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of such filing to the following:

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